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Biotechnology - Argentina Annual Report

2006

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Report Highlights:

Argentina continues to be the third largest producer of soybeans, with an area of 15 million hectares estimated for the 2006 crop season. Argentina is an important ally of the United States in international issues, although there is still a pending disagreement between Monsanto and the Government of Argentina on the royalty collection system for Roundup Ready (RR) soybeans.

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Executive Summary

A decade has now passed since the first commercial releases of genetically modified crops and Argentina, a major producer of agricultural products with at least 98 percent of its soybean area GMO, faces a future with many challenges, where biotechnology is proposed to play a key role as a source of technological solutions to confront these challenges. However, in this scenario, biotechnology is not just a technological tool, its development involves cutting edge-science, political, legal and economic variables as well as external and internal negotiations.

Argentina continues to be the third largest producer of soybeans, with an area of 15 million hectares estimated for the 2006 crop season. No other Latin American country embraced Genetically Modified Crops (GMO) crops as wholeheartedly as Argentina. Soybean harvested area has increased from 36,000 HAS (59,000 MT produced) in 1970 to 5.98 million HAS. in 1995/96 (12.43 MMT produced). The introduction of genetically engineered soybeans in the late 1990s sparked a further expansion of soy production, which now surpasses 15 million hectares.

Argentina continues to be an important ally of the United States in international issues and co-complainant with the United States in the World Trade Organization challenge to the European Union moratorium on GMO crop applications. However, there is still a pending disagreement between Monsanto and the Government of Argentina (GOA) on a royalty collection system for Roundup Ready (RR) soybeans.

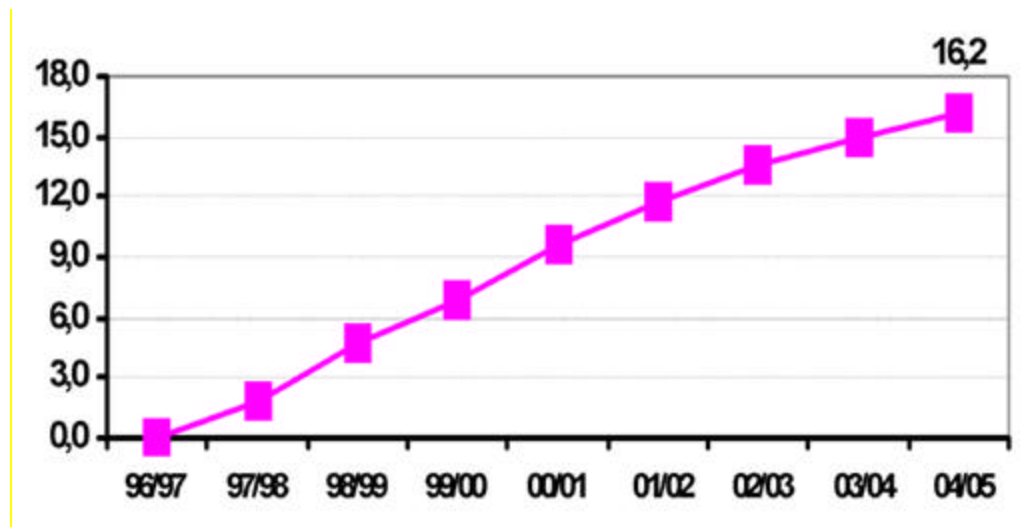
The Argentine biosafety system is a useful model for other countries facing the challenging task of ensuring the safe and responsible use of agricultural biotechnology.

The key agency in the Argentine system is National Advisory Committee of Agricultural Biosafety (CONABIA), within the Secretariat of Agriculture, Livestock, Fisheries, and Food (SAGPyA), pursuant to Resolution 124/91. CONABIA is a multidisciplinary and inter-institutional organization with advisory duties. Its main responsibility is to assess, from a technical and scientific perspective, the potential environmental impact of the introduction of GMOs in Argentine agriculture. CONABIA reviews and advises the Secretariat on issues related to trials and/or the release into the environment of GMOs and other products that may be derived from or contain GMOs.

On February 17, 2006, the Argentine Secretariat of Agriculture issued Resolution 71 that temporary overrides the two resolutions that rule over the right a company has to release and trade genetically modified seed in Argentina. That exemption only applies to those corn varieties that carry the RR event known as GA21. Although Argentina has an effective regulatory framework established through resolutions dictated by SAGPyA, as of yet, no Argentine law on agricultural biotechnology is in force.

Biotechnology Trade and Production

Evolution of the total area planted with GMO in Argentina (millions of hectares)



Source: ASA (Argentine Seed Association)

Argentina is the world's second largest producer of GMO crops after the United States, with ten biotech crop varieties approved for production and commercialization: one for soybeans (Monsanto 40-3-2), two for cotton (Monsanto 531 and 1445) and now seven for corn (Ciba-Geigy 176, AgrEvo T 25, Monsanto 810, NK 603, Novartis Bt 11, Syngenta GA 21 and Dow/Pioneer TC 1507). (Please See Attachment A)

Soybeans

Released in 1996, glyphosate tolerant soybeans were the first GMO crop introduced into Argentine agriculture. Since its release, this technology has been adopted at a very high rate, with an estimate for the current season of 15 million planted hectares, placing Argentina in second place after the United States. The main reason for this rapid adoption is the great economic benefits that RR soybeans provide to the producer. Besides, when the adoption process started, the patent for Roundup (Monsanto's commercial name for glyphosate) expired several years earlier. Thus, there was already a significant increase in competition in the glyphosate market, which translated into significant price reductions. At the same time, the new technologies facilitated the incorporation of double cropping soybeans (following wheat) in many areas where only one crop was planted before the availability of the GMO varieties. (Trigo & Cap -

The Argentine soybean economy is geared almost entirely towards exports. Only two percent of harvested soybeans reach the domestic market, whereas 30 percent is exported as grain and 68 percent is processed by the oilseed industry within Argentina. Ninety-three percent of soybean oil and ninety-nine percent of by-products (meals) are exported.

Evolution of the area planted with GMO in Argentina (thousands of hectares)

Crop	96/97	97/98	98/99	99/00	00/01	01/02	02/03	03/04	04/05
RR Soybean	37	1.756	4.800	6.640	9.000	10.925	12.446	13.230	14.058
Bt Corn	-	-	13	192	580	840	1.120	1.600	2.008
RR Corn	-	-	-	-	-	-	-	-	14,5
Bt Cotton	-	-	5	12	25	10	20	58	55
RR Cotton	-	-	-	-	-	-	0,6	7	105
Total	37	1.756	4.818	6.844	9.605	11.775	13.586	14.854	<u>16.241</u>

Source: SAGPyA

Corn

GMO varieties of lepidoptera tolerant and ammonium-glyphosate tolerant corn were commercially released for the first time in 1998. The adoption of these varieties has also been significant. In the case of Bt corn, benefits are derived from a net increase in production, resulting from the reduction of losses caused by insects and not from increases in the area planted.

The GOA forecasts that producers will plant between 2.3 MHAS of corn this season, although those figures may dramatically change, as it is difficult to estimate the amount that will enter into the formal marketing chain.

Cotton

Biotech cotton adoption represents 40 percent of planted area, according to SAGPyA. Total area estimated by Post for the next crop season is 400,000 HAS.

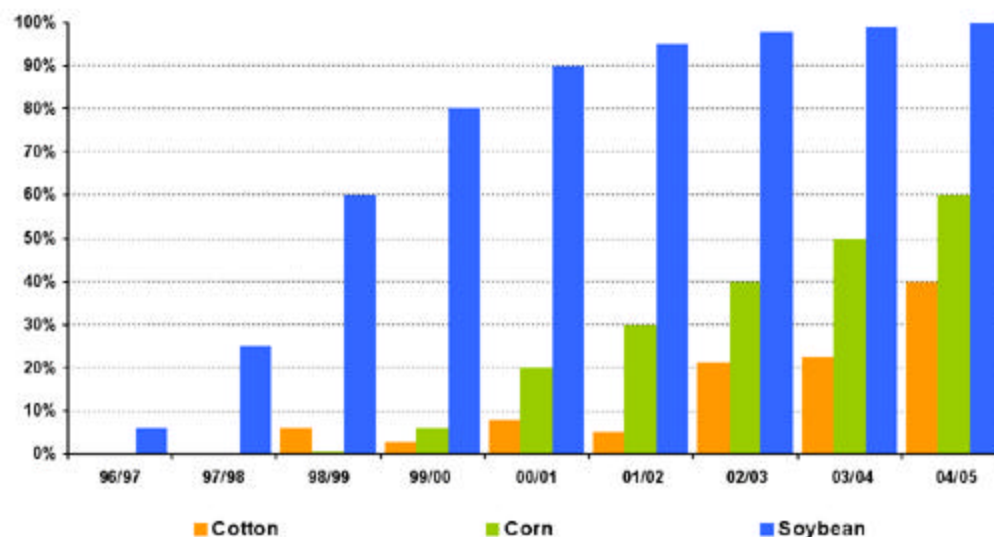
Biotech cotton contains a gene from *Bacillus Thuringiensis* (Bt), a common soil microbe, allowing it to naturally protect itself against insect pests, thereby requiring fewer applications of chemical insecticides.

Although it seems that seed containing the combination of Bt and RR technologies might be approved in the near future, some sources stated that it is doubtful it will be marketed as seed companies have had serious trouble collecting fees and controlling illegal multiplication. Through a research project done by the National Institute of Agricultural Technology (INTA), it was found that in the leading cotton-growing regions of Argentina, biotech cotton required almost 64 percent fewer applications of insecticide when compared to its conventional counterpart.

In Argentina, this research showed that the average cotton grower had a \$65 per hectare advantage (approximately \$26 per acre) using biotech cotton versus conventional cotton. Similar economic advantages have been found in the United States from the use of biotech cotton.

INTA is also conducting research of colored cotton varieties. The release in the market is expected in a few more years and will be focused on niche markets for small and medium producers.

Evolution of the area planted with GMO (Argentina)



Source: ASA (Argentine Seed Association)

Cloned Cows: Cutting edge technology

Argentina has become the first country in Latin America to develop two generations of cloned cows, capable of producing Human Growth Hormone. In March 2006, CONABIA and SENASA (National Service of Agricultural And Food Health and Quality) after their rigorous analysis approved the first step in the process to authorize the production of the human growth hormone from milk. The next step that needs to be completed is the approval by the Secretary of Public Health.

The cloned calves, Pampa Mansa II, Pampa Mansa III and Pampero, developed by the Biosidus Company, carry a gene that produces human growth hormone in milk. The production of this hormone in the clones should help reduce the cost of the medicines, due to the increase in the volumes produced. The milk produced by just one cow can meet the demand of the entire country. It is estimated that 1,000 Argentine children currently require such hormone therapy.

Argentina is one of nine countries that have cloned genetically altered cows since 2002, the year Pampa Mansa was born. The project requires a long-term investment of venture capital, but in an increasingly competitive world, positions Argentina among a select group of countries with high-tech capabilities.

Biotechnology Policy

Biosafety Regulatory System

Argentine biosafety regulatory system is based on the evaluation of the product and not of the process through which it was obtained. Therefore, the evaluation takes place on a case-by-case basis, taking into consideration the process only in those cases where the environment, the agricultural production or the health of humans or animals could be at risk.

The approval process for commercialization of GMOs involves different agencies within SAGPyA:

- National Advisory Committee on Agricultural Biotechnology (CONABIA)

Role: Evaluate of impact in the agricultural ecosystem. Ensures compliance with regulation 39. (Please See Appendix B)

- **National Service of Agricultural And Food Health and Quality (SENASA)**

Role: Evaluate the biosafety of food products derived of GMO crop for human and animal consumption.

- **National Direction of Agricultural Food Markets (DNMA)**

Role: Evaluate commercial impact on export markets by preparing a technical report in order to avoid a negative impact on Argentine exports. DNMA mainly analyzes the status of the event under study in the destination markets in terms of whether the product has been approved or not and, as a result, whether the addition of this event to Argentina's export supply might represent a potential barrier to the access to these markets.

- **National Seed Institute (INASE)**

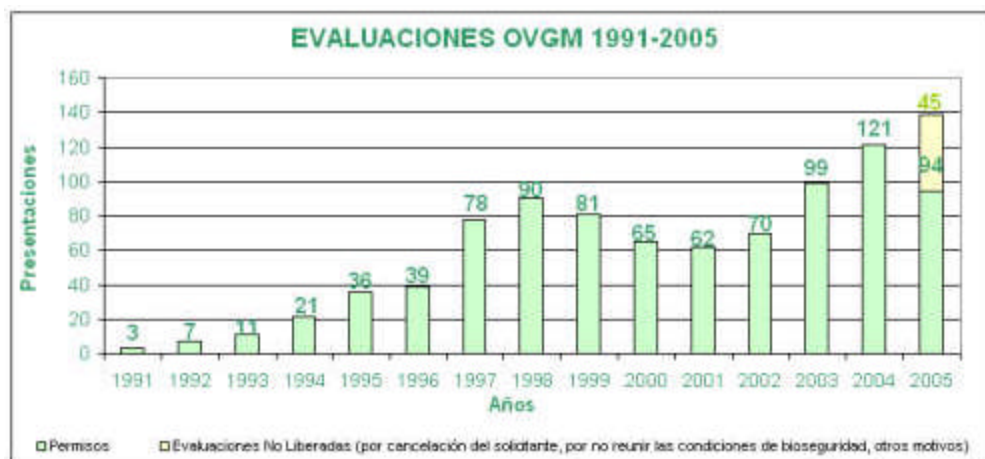
Role: Establish requirements for registration in the National Registry of Cultivars.

Upon completion of all of the steps mentioned above, CONABIA's Office of Technical Coordination compiles all pertinent information and prepares a final report to the Secretary of Agriculture, Livestock, Fisheries and Food for final decision. (Attachments C & D)

It is worth noting that CONABIA is a multi-sectorial organization made up by representatives from the public sector, academia and private sector organizations related to agricultural biotechnology. CONABIA members perform their duties as individuals and not as representatives of the sector they represent, and they are active participants in the international debate of biosafety and its related regulatory processes.

CONABIA has reviewed over 500 permits since its creation, developing new capacities as the sector required. Regarding its legal and institutional framework, CONABIA is an advisory agency that operates pursuant to a resolution by the Argentine Secretary of Agriculture. In absence of a law, this fact prevents the establishment of an adequate system of penalties of those who do not comply with stipulated procedures.

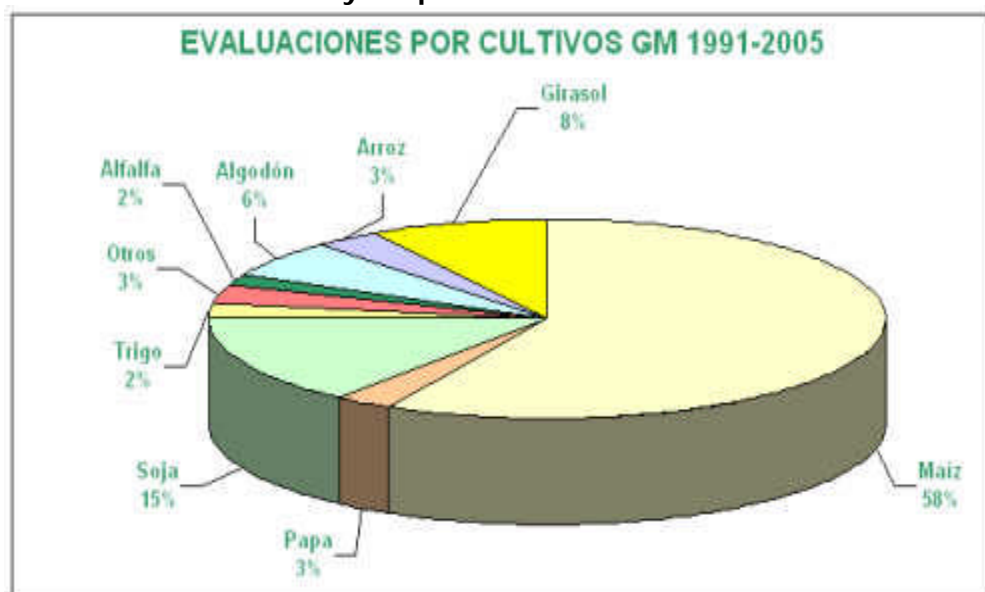
In sum, Argentina was among the earliest countries to establish a biosafety regulatory framework, and there is consensus regarding its effectiveness adjusting to new developments.

CONABIA - GMO Evaluations 1991 - 2005

Source; CONABIA

Note: Green column: authorizations granted

Yellow column: permits not granted (cancellation of applicant, inadequate fulfillment of biosafety conditions or other reasons).

CONABIA Evaluations by Crop

Source; CONABIA

Corn: 58%, Soybeans 15%, Sunflower 8%, Cotton 6%, Rice 3%, Potato 3%, Wheat 2%, Alfalfa 2%, Others 3%

Resolution 71/2006

On February 17, 2006, the Argentine Secretariat of Agriculture issued Resolution 71 that temporary overrides the two resolutions that rule over the right a company has to release and trade genetically modified seed in Argentina. That exemption only applies to those corn varieties that carry the RR event known as GA21.

Secretary of Agriculture Campos, for the next 90 days, eased the seed registration rules for anyone that would like to register a hybrid variety of RR corn, using the Syngenta GA21 gene. This means that a local company can take the GA21 corn (that is resistant to the glyphosate pesticide) and cross it with another type of corn, this cross - or hybrid- can then be registered to the local company. It is uncertain, once a royalties collection system is decided on, how any royalty collections associated with the RR gene would be distributed to the local company or to the international company (Syngenta, etc.).

The reason why this won't affect Monsanto at the moment is registration is only permitted for hybrids with the Syngenta (GA12) gene. When Secretary Campos approved the RR corn last year (Monsanto's NK603 and Syngenta's GA21), it was discovered that there were about 200,000 has that had been sowed with the RR gene prior to the approval (and it appears for as long back as 1998). These 200,000 acres were sown with the Syngenta gene, not the Monsanto gene.

In a press conference given by the Argentine Seed Association (ASA), it was stated that the resolution harms those companies that have invested billions in developing new events and fosters the marginality in the Argentine seed market. While the registration process for a genetically modified variety usually takes between 8 to 9 years in Argentina, Resolution 71 allows companies that have not made any investment in the development of an event, to register a variety in less than 30 days, which is the temporary period of enforcement of this rule.

Taking advantage of Resolution 71, one of the local producers of herbicides that invested approximately 2 million dollars in a seed plant, received the approval for hybrids that contain the gene GA21 registered in Argentina by Syngenta. The company announced that they would be able to sell a bag of seed at a very low price compared to Monsanto's prices per bag, which is logical considering that the local company did not make any effort in developing the event and therefore don't need to recuperate any investment.

Traceability

There is no official system in place. At this stage, only private companies (authorized labs) have the capability to perform the required tests. For example, the National Institute of Agricultural Technology (INTA) does it on private basis.

Labelling

There is no specific regulation in Argentina in reference to labelling GMO products. The current regulatory system is based on the characteristics and identified risks of the product and not in the production process of that product. Therefore, there is no regulation governing the use of labels such as "BIOTECH FREE" or "NON-GMO", which are voluntarily used by the producer.

According to SAGPyA, for the implementation of a regulatory labelling system, the discussion should be based on the type of food product derived from a specific GMO taking into account that:

Any food product obtained through biotechnology and substantially equivalent to a conventional food product, should not be subject to any specific mandatory label.

Any food product obtained through biotechnology and substantially different from a conventional food product for any specific characteristic may be labelled according to its

characteristics as food product, not according to aspects concerning the environment or production process.

Differential labelling is not justified, as there is no evidence that demonstrates that food products produced through biotechnology may represent any risk for the consumers' health. In the case of agricultural products, as the majority of them are commodities; the identification process would be complicated and expensive. The increased production costs as a result of labelling, would end up being paid by the consumers, without assuring that this would represent better information or increased food security.

Stacked events

No defined policy as of yet.

Coexistence

Refuge system is in place. The Argentine Seed Association (ASA), created in 1999 the Insect Resistance Management Program in Bt. The objective of the program is to promote a responsible use of technology in order to delay any potential resistance development and immediately detect any change in the susceptibility of insect population. To carry out this goal, the program is based on three pillars:

Research: Scientists from INTA (National Institute of Agricultural Technology) conduct permanent studies to improve the understanding of pest biology and to monitor the sensitivity to the Bt protein. This way, the tools used to evaluate recommendations regarding resistance management provided to farmers and used to detect any possible change in the susceptibility of the insect population, are in permanent improvement.

Communication: farmers, as users of the technology, have a key role in its preservation, therefore their knowledge is fundamental to achieve a responsible and successful management of Bt corn varieties.

Evaluation of a proper use of technology: the periodic evaluation of farmers to adopt refuges allows to assess the success of the program and to improve the tools to adjust communication. CONABIA approved this system and periodically receives reports submitted by ASA.

Intellectual Property Rights – Royalties

Argentina is a major producer and exporter of agricultural biotechnology products, yet it does not have an adequate and effective system in place to protect the intellectual property rights of new plant varieties or plant-related technology. Penalties for unauthorized use of protected seed varieties are negligible. Judicial enforcement procedures in Argentina likewise are ineffective as a mechanism to prevent the unauthorized, commercial use of protected varieties.

Monsanto, grower organizations, and commodity exporters are at an impasse regarding a solution to the continued high level of saved and illegally traded RR soybeans, which has depressed Monsanto's Argentine operation revenues. In January 2004, Monsanto announced that it would cease investments in and sales of RR soybeans in Argentina. The central issue, according to Monsanto, was its inability to fully collect RR-technology-related royalties from Argentine growers. Monsanto applied for and was denied a patent on RR soybeans, a decision it appealed unsuccessfully with the Argentine Supreme Court. Argentine law currently allows farmers to save seed from one harvest and to use it the following year if a

royalty is paid to the original seed breeder. However, it is illegal to sell, trade, or pass saved seed from one producer to another.

In May 2004, Argentina's National Seed Institute implemented Resolution 44/2004, requiring that each sack of seed be labeled with quantity, unit price, total sales price, and seed species, type or variety. However, the illegal seed sales continued and Monsanto articulated that if an acceptable solution could not be reached with producer organizations and commodity exporters by March 2005, Monsanto would begin to enforce royalty payments on unlicensed Argentine soybeans exports at ports of destination in countries in which Monsanto holds a patent on RR soybeans. In March 2005, Monsanto informed Argentine soybean and product exporters of imminent enforcement actions on unlicensed shipments of soybeans, soybean meal, and other soy products containing the RR gene. This move by Monsanto provoked heated reactions from GOA and Argentine farm organizations.

Since then, SAGPyA, Monsanto and interested parties have tried unsuccessfully to reach an agreement on royalties' collection.

The lack of effective enforcement options for plant variety rights, combined with the absence of patent protection for a significant range of biotech inventions, renders Argentina's intellectual property system inadequate from the perspective of the biotechnology industry.

Biosafety Law

During 2001, the SAGPyA actively cooperated with members of the Argentine Congress in drafting a biosafety law. This draft represented a major improvement on the current situation, since it clearly set forth a conceptual framework, as well as issues and instances to be considered as participants in risk analysis procedures. But due to the institutional and economic crisis that broke out on December 2001, the draft was never discussed in Congress and there is no evidence that it will be in the near future.

International Negotiation Fora

Cartagena Biosafety Protocol

In the international biotechnology negotiation arena, CBP is probably the most significant issue. Argentina signed the Biosafety Protocol in May 2000 in Nairobi, Kenya, but has not yet signed its ratification. Argentina is currently undergoing a consultation process, analyzing and debating with all the involved sectors the position the country will take to this respect.

The overlapping of environmental and human health concerns, as well as commercial implications, have resulted in an extremely difficult negotiation for the countries that, like Argentina, are commodity exporters.

It has to be taken into account that although Argentina has not ratified the BCP, it will have to comply with the commercial obligations when negotiating with countries that are parties.

The CBP has been signed and ratified by 117 countries, 16 of which are developed countries. It is important to mention that most of the undeveloped countries that ratified the CBP, do not possess biosafety regulatory systems and are currently evaluating their possibilities to adjust to the obligations of the CBP. Argentina considers that prior to setting basis of commercial issues, the countries that ratified the CBP should have their respective biosafety framework in place.

Codex Alimentarius

Argentina is strongly working to reach consensus on GMO labelling and traceability, and actively participating to avoid potential trade disruptions and unnecessary cost increases.

Other Agreements

Other important international negotiation areas are the creation of an ad-hoc group on agricultural biotechnology within the framework of the MERCOSUR and the Memorandum of Understanding on biotechnology signed between the GOA and the government of China. During President Kirchner's visit to China in 2004, The Argentine Secretariat of Agriculture, Livestock, Fisheries and Food signed a MOU with the Chinese Ministry of Agriculture, in reference to agricultural biotechnology and biosecurity. The objective of the MOU was to move forward the cooperation, stimulating communication and understanding related to biotechnology policies in both countries. Argentina recently signed a bilateral cooperation agreement with Nicaragua as well.

Through all these agreements, Argentina is trying to create a coordinated dialogue framework for the application of biotechnology policy and biosafety, in a way to avoid negative impacts of trade.

National Fora

Creation of a Biotechnology office within SAGPyA with the objective of centralizing all the information and activities.

CONABIA's development of a 15 year Strategic Plan

The Strategic Plan anticipates a future scenario, which is the context of the vision proposed. Policies are defined and an action plan is outlined for the realization of that vision. In order to define the main issues addressed, objectives are classified by areas of strategic concentration.

The plan proposes to diversify the application of biotechnology, both in the number of tools and in productive activities. It considers creating an appropriate environment (in political, legal and public acceptance issues) for the creation and development of biotechnology-based companies, and also to improve the consolidation of the existing ones. It is proposed to assist the increasing agricultural production, while preserving and improving the life quality of the present and future generations. One of the strengths of the plan resides on its flexibility: the accomplishment of the plan has been based on the implementation of a scheme that is built almost simultaneously along its execution, including the revision of objectives, goals and main actions.

Another strength of the plan is the collective bias of its elaboration: stakeholders of the agricultural and livestock activity took part in different discussions, and they contributed with relevant elements that promoted both the quality and the general acceptance of the document. For several agricultural biotechnology strategic concerns, a regional treatment has been anticipated with the purpose of preserving the regional integration, with attention to local issues, where the relationship with neighbor countries is defined in terms of technological cooperation and commercial exchange or competition.

Announcement of a Biotech Promotion Bill

The Argentine Minister of Economy announced a bill to promote biotech initiatives. The project is to stimulate, through fiscal benefits, research, development and investment in products, services or biotech processes.

Marketing Issues

Public Perception – Consumer's Attitude

While Argentine scientists and farmers are optimistic and enthusiastic about the prospects of using biotech to improve yields and nutritional value of crops while decreasing the input of chemical pesticides, Argentine consumers are concerned about the introduction of GMOs into the human diet, possibly due to a lack of knowledge about genetic engineering as compared to conventional plant breeding and the extensive testing being done to insure the safety of a GMO crop. As yet, Argentine consumers do not see GMOs as a benefit to themselves but they can see these products as economically productive to farmers and multinationals. Therefore, they are hesitant about supporting the technology. As Argentina has been a leader in the adoption of biotechnology, there is an urgent need for dialogue and communication among scientists, farmers, private companies, consumers, government, and regulatory organisms.

Under the *UNEP-GEF* project (United Nations Environment Program – Global Environment Facility), SAGPyA has performed and released a survey among producers and consumers that provided the following results:

Producers: (survey conducted at the two most important local farming shows)

90% of the consulted producers assured that, albeit confusion and hesitation, they knew, worked or at least heard about GMOs,
75% assured that consumption of GMOs DO NOT present any risks to the human health,
12% expressed that they know the Argentine regulatory system, and half of them considered that it is safe,
57% assured that if GOA decides to segregate, they will still use GMO seeds,
82% expressed that biotechnology is a tool that solves problems that no other technology has been able to solve, and
49% assured that biotechnology does not present a serious ethical problem.

Consumers (survey conducted in various supermarkets):

80% are informed mainly thru TV, 55% thru radio and 50% thru newspapers,
13% DO NOT read the label of a product before purchasing it,
60% have confidence in what they consume,
64% of the consulted consumers assured that, albeit confusion and hesitation, they heard about GMOs,
43% agreed on the use of biotech in agriculture
40% Assures that consumption of biotech products poses some risks to human health, and
84% out of that 40% identified the risks

94% of all consulted (both producers and consumers) expressed that the government should provide more information regarding the benefits and risks of biotech products.

Mirror Policy

Argentine Secretary of Agriculture, Miguel Campos, announced his decision to approve Monsanto's Roundup Ready Corn (RR corn) for commercialization, even before the European Union (EU) granted the import authorization. This generated a controversy within the agricultural sector, as the exporters raised their concerns regarding the impact the approval could have in the European market. This represents a step forward against the "mirror policy" with the European Union, or a risky step, as it might represent the potential loss of the European market.

Up until now, Argentina has not approved any commercial GMO plant material unless approved in the European Union. The Argentine media has highlighted that this approval breaks the trend in the Argentine policy towards GMOs and puts away fears about the negative commercial consequences of approving GMOs without the green light from Europe.

Appendix A: GMO Crops Approved in Argentina

Crop	Trait Category	Event/ Applicant	Trait Description	Status
Soybean	Herbicide Tolerant	40-3-2 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed Food Commercialization
Maize	Herbicide Tolerant	T 25 AgrEvo	Resistant to Glufosinate Ammonium	Approved Feed Food Commercialization
Maize	Insect Tolerance	176 Cyba-Geigy	Resistant to lepidoptera	Approved Feed and/or Food Commercialization
Maize	Herbicide Tolerance	NK 603 Monsanto	Gliphosate Herbicide Tolerant	Approved Feed and/or Food Commercialization
Maize	Insect Tolerance	MON 810	Resistant to lepidoptera	Approved Feed and/or Food Commercialization
Maize	Insect Tolerance	Bt 11 Novartis Agrosem S.A.	Resistant to lepidoptera	Approved Feed and/or Food Commercialization
Maize	Insect and Herbicide Tolerance	TC 1507 Herculex DowAgro Sciences	Resistant to European Corn Borer and to Glufosinate Ammonium	Approved Feed and/or Food Commercialization
Maize	Herbicide Tolerance	GA 21 Syngenta	Gliphosate Herbicide Tolerant	Approved Feed and/or Food Commercialization
Cotton	Insect Tolerance	Mon 531 Monsanto	Resistant to lepidoptera	Approved Feed and/or Food Commercialization
Cotton	Herbicide Tolerance	MON 1445 Monsanto	Gliphosate Herbicide Tolerant	Approved Feed and/or Food Commercialization
Soybean	Herbicide Tolerance	A2704-12 A5547-127 Hoechst Schering and AgrEvo S.A.	Glufosinate Amonium Tolerant	Approved for Experimentation and Environment Liberalization

Source: CONABIA

For a complete list of 2005 CONABIA evaluations, please visit:

http://www.sagpya.mecon.gov.ar/new/0-0/programas/conabia/liberaciones_ogm_2005.php

Appendix B: Resolution 39

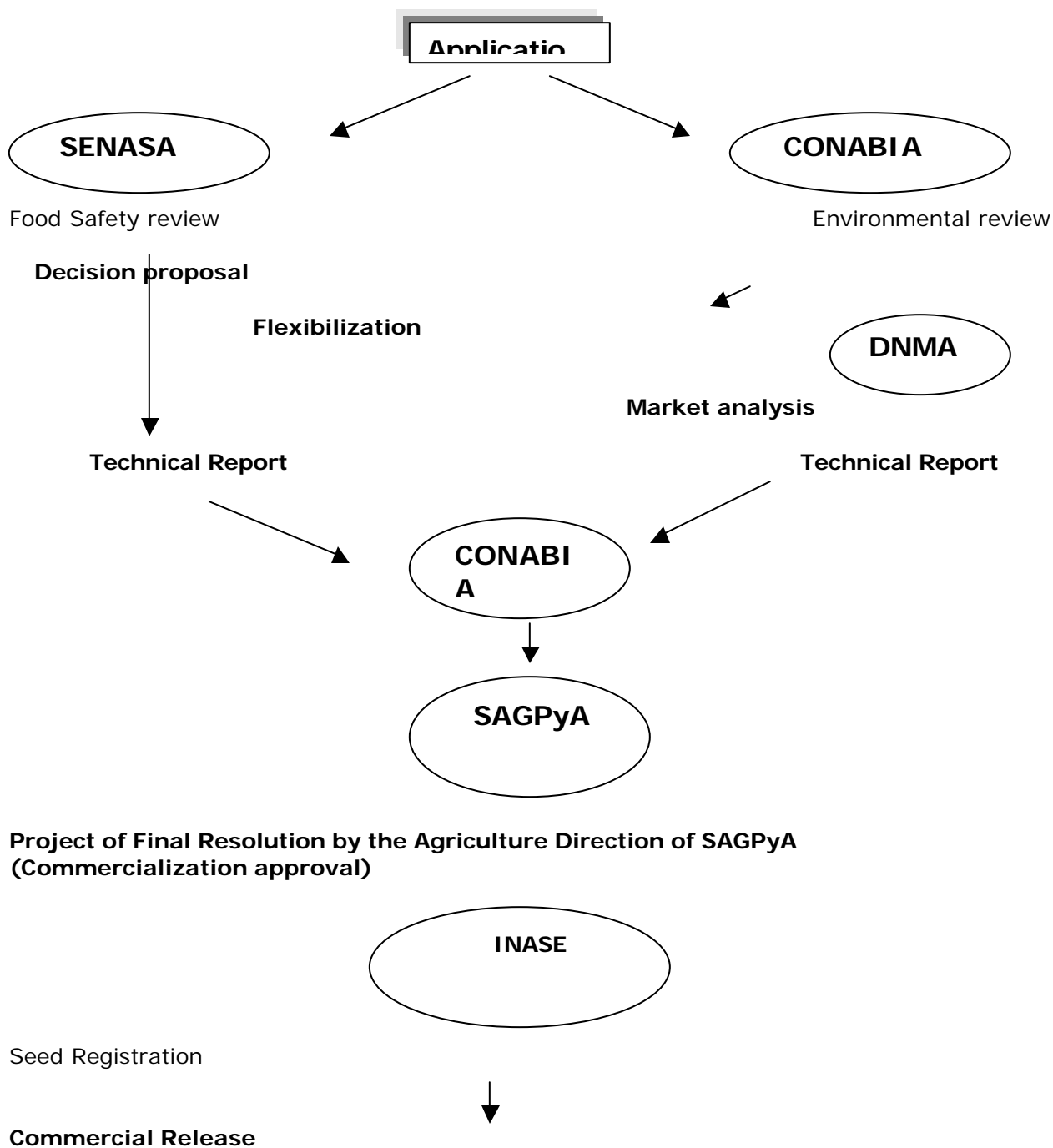
Specifies the conditions under which environmental releases of transgenic material should be conducted. Resolution 39 is part of the general regulatory system governing the existing agricultural regulations in Argentina related to Plant Protection (Decree-Law of Agricultural Production Health Defense, n° 6704/66 and its amendments), Seeds and Phytogenetic Creations (Seed and Phytogenetic creations law, n° 20.247/73 and its regulatory decree), and Animal Health (Law of Veterinarian Products, and Supervision of Creation and Commercialization, n° 13.636/49).

SAGPyA is the authority that issues the licences for experimentation on and/or release into the environment of genetically modified plant organisms, relying on the previous opinion from CONABIA.

- Licences are issued in the following cases:
 - a) Laboratory-greenhouse trials;
 - b) Field trials; and or
 - c) Pre-commercial multiplication of GMOs
- Fifteen (15) copies of the appropriate application must be submitted to CONABIA. The procedure begins in the National Seed Institute at the following address: Paseo Colon 922 - 3° floor - office 349. zip code 1063 - Capital Federal, Buenos Aires, telephone no.: 54-11-4349-2433/2420/2498. fax: 54-11-4349-2417.
- Each copy of the application must be signed by a legally responsible person of the applicant organization, who will assume responsibility for the compliance with all of the conditions under which the pertinent authorization is granted.
- Information included in the summary of the application shall be contained in all other sections of the application, as it is required.
- The assertions in the additional information form must be accompanied by the supporting literature references. All information should be provided in the original language.
- The form must be written in the Spanish language.
- Supplementary information may include reports presented to the competent authorities of foreign countries, with the amendments and additions that may be relevant for the local conditions, as well as references to previous reports presented to CONABIA.
- Upon evaluation of the application, CONABIA shall decide on the suitability of permitting the release of the G MO in question, and shall submit its decision for the approval of the Secretary of Agriculture, Livestock, Fisheries and Food.
- At the end of the period for which the authorization was granted, the applicant shall submit to CONABIA a final report.
- An authorized experiment will be deemed correctly concluded, upon compliance with the following conditions:

- Correct risk management by the applicant,
 - Consistency between the conditions under which the authorization was granted and the conditions observed at the site of experimentation, and/or release by the inspectors appointed by the competent authority; and
 - Submission of the final report.
- Any applicants who had already obtained authorizations for experimentation and/or release into the environment of GMOs, may request through a letter addressed to CONABIA, filed at the National Seed Institute, the flexibility status of the conditions under which the above mentioned permits are granted. Upon granting the flexibility status from the Secretary of Agriculture, Livestock, Fisheries and Food, further releases into the environment will only require the submission of the following information: the area sown, the date of sowing, the site of release, and the harvest date. CONABIA will only recommend that inspections be made at harvest and of the measures taken for the final disposition of the material.
- Obtaining the flexibility status permit will not mean an authorization for seed commercialization. Seed commercialization is subject to the following terms and conditions:
- Authorization to follow more flexible conditions for the granting of permits for release into the environment of GMO material.
 - Compliance with the requirements set forth by the National Seed Institute for registration of the material in the National Cultivar Registry and in the official certification regulations.
 - Compliance, if applicable, with the requirements set forth by SENASA regarding authorizations for the commercialization of agrochemical products.
 - A letter addressed to the Technical Coordination of CONABIA at Paseo Colón 982 - 2° floor - office 220 - zip code 1063 - Federal Capital. Telephone no.: 54-11-4349-2222/2226, fax no.: 54-11-4349-2224, requesting the initiation of the procedure necessary to comply with the requirements under the jurisdiction of SENASA in connection with the use of transgenic material and its derived products for human and animal consumption. SENASA may request from the applicant any information it may deem necessary for the purposes of carrying out the pertinent evaluations.
 - Thereupon, CONABIA will request the technical review of the National Direction of Agricultural Food Markets regarding the convenience of commercialization of the GMO material.
- Upon completion with all of the steps mentioned above, CONABIA's Technical Coordination will compile the pertinent information for the purposes of preparing a final report to the Secretary of Agriculture, Livestock, Fisheries and Food for its final decision.

Appendix C: Commercial Release Approval Procedure for GMOs in Argentina



Appendix D: Field Test Approval Procedure For Gmos In Argentina